

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Esperester, Anke et al.) Art Unit: 1655
Serial No. : 10/743,170) Examiner: Leith, Patricia A.
Confirmation No. : 7746
Filed : December 22, 2003
For : Film Coated Tablet Containing an Extract of Red Vine Leaves
Docket No. : 1/1445

VIA EFS

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ANKE ESPERESTER UNDER 37 C.F.R. § 1.132

I, Anke Esperester, declare: -

1. This declaration is submitted to present evidence in response to the Final Office Action dated March 26, 2008 in the above-referenced patent application.

2. I am employed at Boehringer Ingelheim Pharma GmbH & Co. KG. I am an inventor in the above-referenced patent application.

3. Experiments were conducted under my direction to determine the stability of tablets containing red vine leaf extract and colloidal, anhydrous silica. The experimental data herein provides the results of a comparison study for the stability the disintegration of the tablet at open storage) between two tablets made by different processes.

4. The following experimental data in Table I provide support for the resulting enhanced stability of tablets made by a process where colloidal, anhydrous silica is added during the drying process of an extract of red vine leaves by spray drying.

5. TABLE 1

Comparison Study for the Stability of Red Vine Leaf Extract Tablets Containing Colloidal, Anhydrous Silica

Ingredient	Formulation I (mg/tablet)	Formulation II (mg/tablet)
red vine leaf dry extract	360.000	375.000 (*)
microcrystalline cellulose	219.000	214.000
croscarmellose sodium	18.000	18.000

calcium hydrogen phosphate, anhydrous	30.000	30.000
Crospovidone	-	18.000
colloidal anhydrous silica	4.000	6.000
magnesium stearate	9.000	9.000
Hypromellose	11.383	11.383
glyceryl tristearate	1.138	1.138
titanium dioxide	0.783	0.783
Talc	3.131	3.131
ferric oxide	1.565	1.565
disintegration of tablet at open storage at 25°C / 60% r.h.	7 days	27-33 days
disintegration of tablet at open storage at 30°C / 70% r.h.	2-3 days	4-6 days

(*) contains 15mg colloidal anhydrous silica

6. The data presented in Table I show that the tablet of Formulation II made by adding 4% by weight of colloidal, anhydrous silica to the red vine leaf extract during its drying by spray drying, remained stable at open storage at 25 °C / 60% r.h. for 27-33 days before the tablet disintegrated, while the tablet of Formulation I made by drying the red vine leaf extract prior to the addition of colloidal, anhydrous silica, remained stable for only 7 days. Furthermore, at 30 °C / 70% r.h. the tablet of Formulation II remained stable for 4-6 days while the tablet of Formulation I remained stable for 2-3 days. This shows that the stability of a tablet containing dried red vine leaf extract and colloidal, anhydrous silica is significantly affected by the process in which the tablet is made.

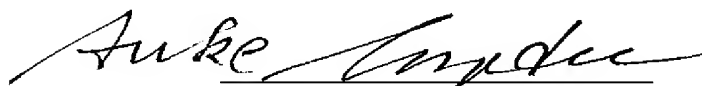
7. The experimental data surprisingly demonstrate the addition of colloidal, anhydrous silica to red vine leaf extract during the drying process of the red vine leaf extract by spray drying results in a tablet with unexpectedly superior stability than those tablets where the colloidal, anhydrous silica is not added during the drying process.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the likes so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that

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Declaration under 37 C.F.R. § 1.132 dated august 20, 2008

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such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

A handwritten signature in cursive script, reading "Anke Esperester", written over a horizontal line.

Anke Esperester

Date: 08/20, 2008